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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER

SORKIN, DAVID L

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 07/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,054

Applicant(s)

MERINO ET AL.

Examiner

David L. Sorkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 20 June 2003.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-4 and 7-17 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 27 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 8.

4) ☐ Interview Summary (PTO-413) Paper No(s): _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-4 and 7-17 in Paper No. 7 is acknowledged. The traversal is on the grounds that search and examination of all claims would not be burdensome. While it is true that both inventions I and II are classified in class 494, they are classified in different subclasses. Search of the entire class 494 is never (to the best of the examiner's knowledge) performed for any particular invention, but instead search is limited to certain subclasses in class 494. Of course, subclasses in classes other than 494 may also be searched as appropriate. In the instant application, if the method claims were to be searched, the search would focus upon the steps of substituting one rotor core for another in a method where a product is processed by both rotor cores. This search has no relevance to the apparatus claims, because they are directed to a single rotor (and combinations and subcombinations thereof) or centrifuges with no positively recited rotor. In summary, while both inventions I and II broadly relate to centrifugation, the search would be much different for the two inventions because many of the method steps have no relevance to the apparatus invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Drawings

2. Figs. 7, 9, 11, 13, 17-19, 21, 23, 25 and 26 are objected to as containing inaccurate, self-contradictory numerical information, perhaps due to the use of the

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erroneous mathematics presented in the instant specification (discussed below under the heading "Specification"). Specifically:

a. Regarding Fig. 7 it is stated that the half angle theta-T of the fins is (rounding off) 0.9 degrees and the half angle theta-B is 0.6 degrees. It is also stated that the top fin distance is 0.083 inches and the bottom fin distance is 0.114 inches. However, if the top fin angle is larger than the bottom fin angle, the top fin distance must be larger than the bottom fin distance. Likewise, Figs. 11, 17, 18, 19 and 21 contain analogous contradictory information.

b. More generally, the distance of a cord is necessarily less than the distance of the corresponding arc (shortest path is straight line), so the angle (theta-T or theta-B) in radians multiplied the corresponding radius (angle in radians X radius = arc length), must be greater than the corresponding fin dimension (D2 or D1) respectively.

However, considering theta-B in Fig. 7: $(2 \times 0.0106 \times 2.145 \text{ inches} = 0.04547 \text{ inches})$ is less than the stated D1, which is 0.114 inches. Likewise see D1 in Figs. 9, 11, 13, 17, 18, 19, 21 and 23, which are all inconsistent with the corresponding theta-B values.

c. Differently stated, if theta-T is known, D2 may be computed (based upon the definition of sine, see page A-5 of "Physics for Scientists and Engineers", section IV-4, subsection 1) as: $\sin(\theta_T) = D2/2R2$. Likewise, $\sin(\theta_B) = D1/2R1$. Taking the data from Fig. 7, the values for θ_T , R2 and D2 are consistent with this analysis. That is, $\sin(0.91527 \text{ degrees}) = .083/(2 \times 2.598)$. However, such analysis shows that the values for θ_B , R1 and D1 are not consistent with one another. Likewise, in each of Figs. 9, 11,

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13, 17, 18, 19, 21 and 23, the values for Θ_B , R1 and D1 are not consistent with one another.

d. Though in the specification and drawings it is stated that $D1 = D2 + 0.031$ inches, this is not consistent with the values of D1 and D2 for Figs. 9, 13 and 23.

e. Regarding figures 15 and 25, if there are no fins, as the calculations assume, how can the core have an inner and (different) outer radius? There would only be one radius and there would be zero void volume. As seen in corresponding structural figures 14 and 24, the R1 circle cuts through solid rotor material; therefore, it is incorrect to assume a void between the R1 and R2 circles.

f. It is further noted that Fig. 7, incorrectly indicates that $8470.4 \text{ mm}^3 = 102 \text{ mL}$ rather than 8.47 mL and that $2543.2 \text{ mm}^3 = 31 \text{ mL}$ rather than 2.54 mL . Similar errors are present in Figs. 9, 11, 13, 15, 17, 18, 19, 21, 23 and 25. It is especially noted that the "Available Volume" concluding statement incorrectly converts cubic millimeters to liters in every case. Particularly, regarding Fig. 7, $3,199.47 \text{ mm}^3 = 0.0032 \text{ L}$, not 3.2 L ; regarding Fig. 11, $8,369.29 \text{ mm}^3 = 0.0084 \text{ L}$, not 8.4 L ; regarding Fig. 11, $3,192.78 \text{ mm}^3 = 0.0032 \text{ L}$, not 3.2 L ; regarding Fig. 13, $7,972.37 \text{ mm}^3 = 0.008 \text{ L}$, not 8.0 L ; regarding Fig. 15, $295.69 \text{ mm}^3 = 0.0003 \text{ L}$, not 0.3 L ; regarding Fig. 17, $1,597.94 \text{ mm}^3 = 0.0016 \text{ L}$, not 1.6 L ; regarding Fig. 18, $774.84 \text{ mm}^3 = 0.0008 \text{ L}$, not 0.8 L ; regarding Fig. 19, $380.95 \text{ mm}^3 = 0.0004 \text{ L}$, not 0.4 L ; regarding Fig. 21, $1,572.11 \text{ mm}^3 = 0.0016 \text{ L}$, not 1.6 L ; regarding Fig. 23, $3,882.46 \text{ mm}^3 = 0.0039 \text{ L}$, not 3.9 L ; and regarding Fig. 25, $147.83 \text{ mm}^3 = 0.0001 \text{ L}$; not 0.1 L . These erroneously converted volumes are cited in Fig. 26 and throughout the specification. See especially pages 31-35 and 41-45.

g. Fig. 26 is also objected to because it reports volumes calculated based upon the erroneous data discussed above.

h. Figs. 7, 9, 11, 13, 17-19, 21, 23 and 25 are further objected to because they refer to "W1 Fin Volume Component 1" and "W2 Fin Volume Component 2" without any explanation in the drawings or specification of what these two components are.

3. The drawings are objected to under 37 CFR 1.84(p)(1), which states "Reference characters... must not be... enclosed within outlines, e.g. encircled". See Figs. 2A and 2B which include encircled reference characters.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(q), which states: "Lead lines are required for each reference character except for those which indicate a surface on which they are placed". See "110b" in Fig. 6, "110c" in Fig. 8, "110d" in Fig. 10, "110e" in Fig. 12, "110g" in Fig. 16, "110h" in Fig. 20 and "110i" in Fig. 22.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference signs mentioned in the description: "110" (see for example page 22, line 5).

6. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

7. The specification is objected to as failing to comply with 37 CFR 1.58(a), which states "The specification... shall not contain drawings". The drawing on page 23 must

be omitted from the specification. A corresponding figure may be added to the drawings.

8. The specification is objected to under 37 CFR 1.71(b) because the specification includes inaccurate mathematical equations. Particularly, on page 23, the formula:

$$2\Theta_T = R_2^2 + R_2^2 - 2(R_2)(R_2)\cos(2\Theta_T)$$

is not an accurate application of the law of cosines to the described situation. It omits the critical parameter "D2" and implies that Θ_T can be determined knowing only R_2 . An accurate application of the law of cosines to the described situation would instead be:

$$D_2^2 = R_2^2 + R_2^2 - 2(R_2)(R_2)\cos(2\Theta_T)$$

which is in no way equivalent to applicant's equation. See page A-6 of "Physics for Scientists and Engineers", section IV-5, subsection 7, equation 2. Next, supposedly by solving the first equation mentioned above, applicant recites that equation:

$$\Theta_T = \cos 1[(1-D_2^2)/2R_2^2]/2$$

which in some sense suggests that applicant was aware of the correct application of the law of cosines mentioned above, since the supposedly solved equation has a " D_2^2 " term; however, the "solved" equation is also inaccurate and, firstly, must rather than "cos1" read -- arccos -- or -- \cos^{-1} --. This change still would not be sufficient to make the equation accurate, however. It is considered that a correct solution to the correct application of the law of cosines would be:

$$\Theta_T = \cos^{-1}[(1 - (D_2^2/2R_2^2))/2],$$

which is not equivalent to applicant's equation, with or without the correction of "cos1" to read -- \cos^{-1} --. Likewise, it is considered that the equation on the first line of page 24

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is inaccurate, but the examiner is aware of no way of "correcting" it while maintaining the $\Theta_T + \Theta_B$ concept. Also, the meaning of the word "Schwenk" is unclear in the equation.

9. All specific references in the specification to the inaccurate information contained in the drawings (such as rotor volumes), discussed above, are also objected to. See especially pages 31-35 and 41-45.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-4 and 7-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is considered that the disclosure is so replete with mathematically errors that one skilled in the art would conclude that applicant was not in possession of the invention at the time of filing. Applicant's conclusions concerning volume capacity of rotors and the "scalability and linearity" of separation achieved by such rotors of different volume would be seriously doubted due to the materially inaccurate equations, calculations and data discussed above with regard to the drawings and specification. Each and every calculation of rotor volume (see Figs. 7, 9, 11, 13, 17-19, 21, 23 and 25) involves substantive errors (as pointed out

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in the drawing objections above). Each of the three equations for calculating fin volumes (see pages 23 and 24) is erroneous as discussed in the objections to the specification above.

12. Claims 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

a. Claims 7-12: While it is unclear what is being claimed in claims 7-12, as discussed below with regard to the second paragraph of section 112, as best understood, these claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Particular, it is considered that the specification does not enable "means for setting a number of parameters and adjustment means operable at the set parameters", recited in claim 7. In claim 8 it is further stipulated that the "adjustment means enables substitution of a rotor core of varying configurations". One skilled in the art could not make or use these means without knowing the corresponding structures. The specification fails to describe corresponding structures for these means-plus-function recitations. The specification states on page 19, lines 2-3 "Adjustment means are provided for setting parameters"; however, claim 8 recites "means for setting a number of parameters *and* adjustment means" (emphasis added). In any case, no particular structures are associated with either the "means for setting" or the "adjustment means". While the specification discusses changing the volume of a rotor of the centrifuge, this is only accomplished by

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replacing parts of the centrifuge. No disclosure of a structure for carrying out such a replacement process is described in the specification.

b. Claim 13: Claim 13 recites "a rotor core *freely rotatable* within the rotor housing" (emphasis added). While the rotor assembly (2) of the invention, including both the housing and the core, is understood to be rotatable within "tank assembly (1)", rotation of the core (6) with respect to the rotor housing (5) is not enabled. Oppositely, Figs. 2A and 2B, would convey to one skilled in the art that the rotor housing (5) and core (6) are fixed relative to one another by pins, similar to "pins 23" of Gibson et al. (US 3,430,849). Without any explanation in the instant specification of how the core (6) is made to rotate freely with respect to the rotor housing (5), and considering the substantial problems, such as fluid agitation, that such a situation would cause, it must be considered that such a limitation is not enabled. The examiner believes that applicant unintentionally claimed such a limitation, but applicant may correct the examiner if such is not the case.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 7-12, 16 and 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

15. Claims 7 recites "means for setting a number of parameters and adjustment means operable at the set parameters". In claim 8 it is further stipulated that the "adjustment means enables substitution of a rotor core of varying configurations". It is

unclear what the corresponding structures for these means-plus-function recitations are and it is therefore unclear what the scope of claims 7-12 is.

16. In claims 9 and 10 there is lack of antecedent basis for "each respective rotor core". Also, it is unclear if any of the rotor cores are recited as elements of the claimed apparatus, or if they are meant to relate to a function of a means-plus-function limitation (such as the means for adjusting). Also, in claim 10, there is lack of antecedent basis for "the plurality of fins".

17. In claim 11, there is lack of antecedent basis for "the rotor core". It is unclear if a rotor core is required structural element of the claimed apparatus or if the rotor core is being mentioned with regard to an intended use or the function of a means-plus-function recitation.

18. Regarding claims 16 and 17, independent claim 14, from which claims 16 and 17 depend, requires "a plurality of fins"; however, claim 16 recites "said plurality of fins are between 0 to 36 in number" and claim 17 recites "said plurality of fins are between 0 and 6" in number. It is unclear what the scopes of claims 16 and 17 are, because a rotor with no fins does not have a plurality of fins. It is considered that a plurality of fins requires at least two fins.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1-4, 7-12 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibson et al. (US 3,430,849). Claim 1 recites "A centrifuge apparatus" but does not further require any other structural elements. Instead it stipulates that the centrifuge is "operable at certain predetermined parameters" and discusses what type of rotor one might choose to operate the centrifuge with during intended operations. Gibson ('849) discloses a centrifuge apparatus (see title). Various operational parameters are discussed in col. 5, lines 55-75. It is considered the discussion in the claim of what rotors the claimed apparatus is "usable with" does not distinguish the claimed apparatus from the prior art because no rotor is positively recited in the claim. Claims 2 and 3 merely discuss rotors which are not part of the claimed apparatus. Likewise claim 4 requires "A centrifuge apparatus" but does not further require any other structural elements. Instead it stipulates that the centrifuge is "operable at certain predetermined parameters" and discusses what type of rotor one might choose to operate the centrifuge with during intended operations. Gibson ('849) discloses a centrifuge apparatus (see title). Various operational parameters are discussed in col. 5, lines 55-75. It is considered the discussion in the claim of what rotors the claimed apparatus is "usable with" does not distinguish the claimed apparatus from the prior art because no rotor is positively recited in the claim. While it is unclear what is being claimed in claims 7-12, these claims have been considered with regard to the prior art to the extent possible. Regarding claims 7 and 8, Gibson ('849) discloses a centrifuge apparatus for separating particles of a product (see col. 1, lines 28-34) having a rotor assembly (1,11,12,13,18,19). As noted above with regard to section 112, the

corresponding structures for the "means for setting" and "adjustment means" are unclear; however, the rotor assembly is threadedly assembled (see Fig. 2; col. 3, line 31) and one could substitute various rotor cores to adjust the volume if one chose to do so. Regarding claim 9, the rotor assembly includes a core (11) with a plurality of fins (16) arranged in a predetermined manner (see Fig. 3). Regarding claim 10, a plurality of fins (16) are equidistantly spaced apart (see Fig. 3). Regarding claims 11 and 12, six fins (16) extend radially outwardly from a rotor core (11) (see col. 3, lines 26-30; Fig. 3). Note: while claim 13 is not rejected as anticipated by Gibson ('849) because Gibson ('849) does not disclose the limitation of claim 13 which is not enabled as discussed above with regard to section 112, first paragraph, it is noted for the record that Gibson ('839) otherwise discloses all the limitations of claim 13. Specifically, Gibson ('849) discloses a rotor assembly (1, 11, 12, 13, 18, 19) rotatable in a centrifuge assembly (2) comprising a rotor housing (1, 12, 13, 18, 19) of a defined volume and a rotor core (11) including a plurality of product flow distribution channels (15) and a plurality of fins (16) extending radially therefrom of a predetermined configuration to define a volume of the predetermined rotor core (see Figs. 2 and 3). Regarding claim 14, Gibson ('849) discloses a rotor core (11) including a plurality of product flow distribution channels (15) and a plurality of fins extending radially therefrom of a predetermined configuration to define a predetermined volume of the rotor core (see Fig. 3). Regarding claim 15, the fins are equidistantly spaced apart from each other (see Fig. 3). Regarding claims 16 and 17, the number of fins is six (see col. 3, lines 26-30; Fig. 3).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 8:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David Sorkin

July 7, 2003